

Application No.: 10/658,962
Attorney Docket No.: 49321-102
First Applicant's Name: Mendy S. Maccabee
Application Filing Date: September 8, 2003
Final Office Action Dated: May 22, 2009
Date of Response: August 24, 2009
Examiner: Jennifer M. Kim

REMARKS

Claims 1, 6-8, 21, and 24-28 are pending in this application. In this response, claims 1, 6, and 28 have been amended. No claims have been cancelled or added. Accordingly, claims 1, 6-8, 21, and 24-28 remain under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Examiner Interview Summary

Applicants thank the Examiner for extending the courtesy of a telephone interview had between Mika Mayer and Barry Davison on July 23, 2009. During the interview, Biesalski (U.S. 5,556,611), Belloni (U.S. 6,339,107), and Cazares were discussed and, specifically, how they fail to describe the treatment of sinus disease or promotion of sinus wound healing, as required by the claims. Additionally, potential claim amendments were discussed, which the Examiner agreed would further distinguish the instant claims from the cited references. Those amendments included positively reciting topical delivery of a vitamin A composition to a sinus cavity (as opposed to a sinus mucosa) as well as removing the phrase “nasal mucosa” from the claims. The applicants have amended the claims accordingly, and the amended claims are reflected in the Listing of Claims above. In addition, Ms. Mayer and Mr. Davison discussed the distinction between nose and throat cavities and sinus cavities. Further explanation, including a figure that illustrates this distinction, is provided below.

Claim Rejections-35 USC §103(a)

Claims 1, 6-8, 21, and 24-28 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Biesalski (U.S. 5,556,611) in view of Cazares (March 2002) and Belloni (6,339,107). The Office asserts that Biesalski’s description of treating the epithelia of the nose-throat cavity overlaps with the treatment of sinus mucosa. Furthermore, although Biesalski does not expressly teach the promotion of sinus wound healing, the Office states that this would have been obvious to one of ordinary skill in the art in view of the teachings of Cazares. The Office

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also states that although Biesalski does not teach a non-aerosol, depot formulation of retinoic acid and ciliated epithelial damage due to the surgical interventions set forth in claims 7 and 24-27, it would have been obvious to one of skill to modify the aerosol formulation of Biesalski to a topical depot formulation as taught by Belloni for treating damaged mucous membranes due to any cause, including surgical intervention.

Applicants disagree with this rejection. Claim 1 has been amended to recite that the vitamin A composition is topically delivered to a sinus cavity. The cited references, alone or in combination, lack disclosure of this claimed delivery location. The cited references also fail to disclose the claimed treatment indications (treatment of sinus disease or promotion of sinus wound healing). In addition, the Office Action fails to articulate any reasoning or rational underpinning to support a legal determination of obviousness, which includes a failure to articulate any reason why an ordinary artisan would combine the cited references in order to achieve treatment of sinus disease or promotion of sinus wound healing by topically delivering a composition comprising vitamin A to the sinus cavity.

Failure to Disclose Delivery of Vitamin A to the Sinus Cavity

As amended, independent claim 1 recites that the vitamin A composition is topically delivered to a sinus cavity. The sinus cavity is lined with sinus mucosa. Applicants submit that obviousness has not been established because as stated above, the cited references, alone or in combination, lack description of vitamin A delivery to the sinus cavity.

The Office contends that Biesalski's description of treating the epithelia of the nose-throat cavity overlaps with the treatment of sinus mucosa. Applicants disagree and respectfully point out that the nose and throat cavities are distinct from the sinus cavities. Provided below is a figure showing a cross-sectional view of structures in the head and neck (<http://media-2.web.britannica.com/eb-media/78/74278-004-77CECC8B.jpg>). As illustrated in the figure, the sinus cavities, e.g., the frontal and sphenoid sinus cavities, are distinct chambers, separate from the nose (nasal) cavities and the throat. They are spaces within certain cranial bones and are named according to the bones in which they are located. Thus, the sphenoid sinus is within the

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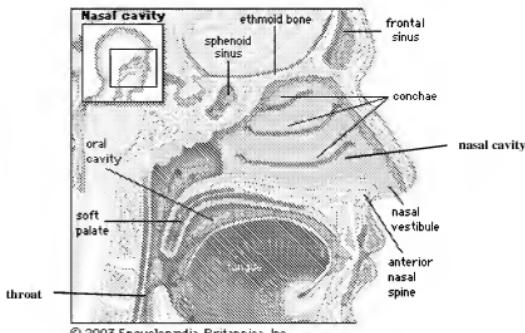
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sphenoid bone and the frontal sinus is within the frontal bone. The nasal cavities are also distinct spaces, but they are formed by the borders of different cranial bones. Thus, vitamin A delivery to the nose-throat cavity is not the same as vitamin A delivery to the sinus cavities (or even the sinus mucosa contained therein). Applicants reiterate that because Biesalski fails to address the specific location of treatment, it cannot be said that Biesalski renders the instant claims obvious.



Cazares teaches topical application of tretinoin to the skin for the treatment of cutaneous ulcers. Belloni, which is also cited by the Office, teaches delivery of 13-cis-retinoic acid to the lung for treating pulmonary diseases. Thus, neither Cazares nor Belloni cures the defect of Biesalski.

Failure to Disclose Treatment Indications

Each of the currently pending claims recites a method for treating a sinus disease or promoting sinus wound healing. Biesalski clearly fails to disclose either of these treatment indications. The pharmaceutical preparations described by Biesalski are used for therapy of lung diseases such as bronchial carcinomas, squamous metaplasia caused by acute and chronic bronchitis, acute and chronic functional disturbances due to impairment of the tracheobronchial epithelium following inhalation of dusts and gases damaging the mucous membranes, and bronchopulmonary dysplasia of newborn children (column 10, lines 24-30, and column 13, lines

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55-60). Nowhere does Biesalski teach, describe, or even suggest the treatment of any type of sinus disturbance or treatment of the sinus cavity. Applicants reiterate that because Biesalski fails to address the specific conditions or area of the body to be treated, i.e., the sinus cavities, it cannot be said that Biesalski renders the instant claims obvious.

Cazares discloses the treatment of non-healing cutaneous ulcers on the skin. Because Cazares also fails to teach, describe, or suggest the treatment of the sinus cavity, sinus disease, or promoting sinus wound healing, combining it with Biesalski does not cure Biesalski's deficiency. There is also no reason to combine Cazares with Biesalski because there is clearly no anatomical association between cutaneous ulcers and/or skin treatment and the sinus cavities.

Moreover, one of skill would not think to combine the cited references because there is no logical connection between the treatment of cutaneous ulcers as disclosed by Cazares and the treatment of lung diseases as disclosed by Biesalski. In addition to addressing separate tissue types, Cazares and Biesalski address different medical conditions. For example, non-healing cutaneous ulcers are associated with medical conditions that include diabetes, venous or arterial insufficiency, chronic pressure, and/or trauma. Contrastingly, the lung diseases described by Biesalski are associated with medical conditions that include viral or bacterial infection, inflammation, or cancer. Accordingly, Applicants submit that the claims are not obvious in view of the combination of Biesalski and Cazares.

With respect to Belloni, Applicants maintain that obviousness has not been established because one of skill would not look to combine Biesalski with Belloni for any reason. This is because, as previously discussed in Applicants' prior Office Action responses, Belloni teaches away from Biesalski. The purpose of Belloni's formulation is to treat COPD using a compound that is non-toxic at therapeutic levels (column 5, lines 27-43). Belloni advises against administering all-trans retinoic acid (ATRA), which is used by Biesalski, because of its systemic toxicity (column 3, lines 60-63). Instead, 13-cis-retinoic acid is administered because it has a high therapeutic index when compared to ATRA (column 12, lines 22-25, and Example 6).

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In another aspect, the claims have not been rendered obvious because Belloni fails to teach, describe, or suggest the treatment of sinus disease or promotion of sinus wound healing. As previously stated, Belloni describes the treatment of lung disease, specifically, chronic obstructive pulmonary disease (COPD). Belloni defines COPD as a disease where the lungs are obstructed due to the presence of at least one disease selected from asthma, emphysema, and chronic bronchitis (column 2, lines 12-14). The treatment of emphysema is particularly highlighted because no effective method exists (column 3, lines 1-2). Belloni further defines emphysema as a disease where the alveoli of the lung are destroyed (column 2, lines 25-26). Thus, even if combined, Belloni does not cure the deficiency in Biesalski.

In view of the above, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

CONCLUSION

In view of the above, all pending claims in this application are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

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Respectfully submitted,
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